

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 1-6, 8-11, 13-18, 20-22, 24-30, 34-35, and 38 are currently being amended.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1-30 and 32-38 are now pending in this application.

**Rejections Under 35 U.S.C. §102**

**A. U.S. Patent No. 3,675,846 to Drucker**

Claims 1-6, 11, 13-18, 24-29 and 34 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,675,846 to Drucker (hereinafter Drucker). Applicants respectfully submit that this rejection is mooted by amendments made herein to the claims.

Applicants have amended each of independent claims 1, 13, 24, and 34 to recite a “first reinforced mating section.” Support for this amendment can be found within the original specification at least in the illustrations of FIG. 2C, FIG. 6A, and FIG. 6B. According to § 608 of the M.P.E.P., an applicant may rely for disclosure upon the specification with original claims and drawings, as filed. Each of these figures, best illustrated in FIG. 2C, illustrate in cross section a portion of the bag situated near the central, or axial opening. Referring to FIG. 2C, each of the first side 202 and the second side 204 of the bag 200 includes a respective raised portion 210. As illustrated, the raised portion 210 is thicker than the cross section of either side of the bag. According to Merriam-Webster Online dictionary, available on the Internet at URL <http://www.merriam-webster.com>, “reinforce” is a transitive verb, meaning to strengthen by

additional assistance, material, or support. FIG. 2C illustrates the raised portion has having either additional material or support (*i.e.*, it is thicker than the surrounding bag). As it is the raised portion that is described and illustrated as mating with a recess 302 (FIG. 3B) on the hub, the reinforced region of the bag corresponds to the reinforced mating portion, as recited in the amended claim. Applicants believe that no new matter is added by way of this amendment.

Turning briefly to Drucker, a continuous-flow centrifuge head is described including a plastic bag that rotates with the chamber serving as a liner for the chamber (Col. 2, lines 56-57). In particular, “the plastic bag is suspended around the neck 55a on the central bracket.” As further described by Drucker, the bag may be supported by cords around its neck and around the neck 55a of the bracket, or by an O-ring in the upper annular groove 55b. (Col. 2, lines 52-60). Thus, an open end of a plastic bag is positioned against the neck 55a of the central bracket and held into place using cords. As illustrated in FIG. 3 of Drucker, the plastic bag may follow the interior contour of the chamber, including a portion positioned within the upper annular groove 55b, described as being held in place by an O-ring.

Drucker does not describe any portion of the bag as being “reinforced” in any way. To the contrary, Drucker appears to rely upon a substantial flexibility of that portion of the bag adjacent to the central opening. The Office action suggests at page 2, lines 15-16 that the very portion of the bag “adjacent 55a and/or 55b and/or the recess near 55b,” corresponds to Applicants’ mating portion. As illustrated in FIG. 3, the neck of the bag conforms to multiple sharp bends in the central neck 55, from a top surface of the bag, into an upper annular groove 55b, around a neck 55a of the bracket, and into the upper annular groove 55b (col. 2, ll. 58-60). If Drucker’s bag were reinforced in any manner similar to that recited in Applicants’ amended claims, it is unlikely how it could be contorted in the manner described and illustrated in FIG. 3.

Thus, Drucker fails to anticipate Applicants’ amended claim 1, at least because Drucker does not describe “a first reinforced mating portion positioned adjacent to the central opening” as recited in Applicants’ amended claim.

Thus, Applicants submit that all of the recited elements in independent claim 1 as amended herein are not found in Drucker, at least because Drucker fails to disclose a bag having “a first reinforced mating portion positioned adjacent to the central opening.” Applicants respectfully request withdrawal of the rejection of independent claim 1.

Independent claims 13, 24, and 34 have also been amended to recite similar limitations as claim 1 and are therefore not anticipated by Drucker for at least the same reasons as claim 1.

Dependent claims 2-6 and 11 depend directly or indirectly from amended claim 1, dependent claims 14-18 depend directly or indirectly from amended claim 13, and dependent claims, and 25-29 depend directly or indirectly from amended claim 24. Accordingly, each of dependent claims 2-6, 11, 14-18, and 25-29 contain all the elements of their respective independent claims and are not anticipated by Drucker for at least the same reasons. Applicants respectfully request withdrawal of the rejection of claims 2-6, 11, 14-18, and 25-29.

**B. U.S. Patent No. 4,610,369 to Mercier**

Claims 1-23 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,610,369 to Mercier (hereinafter Mercier). Applicants respectfully submit that this rejection is mooted by amendments made herein to the claims.

The Office Action at the bottom of page 3 equates Applicants’ bag to the bellows described by Mercier. Each of Applicants’ independent claims 1 and 13 as amended herein now recites that the bag has a “first reinforced mating section.” The bellows structure described by Mercier is completely different from the circular enclosure recited in Applicants’ claimed invention. Even if the bellows were considered to be a substantially circular structure, the bellows fails to include a reinforced mating section, as recited in Applicants’ amended claims.

That portion of the bladder 13 positioned adjacent to the central opening is described as flanges 39, 40 that snugly encompass the outer surface of the guide tube. (Col. 4, ll. 12-13). It is not clear from the description or the figures that the flanges are reinforced in any way. Rather

than relying upon reinforced flanges, Mercier relies upon a separate structure to securely retain the flange in position to the guide tube. Namely, Mercier describes using an O-ring 42 to force a portion of the flange material into an associate annular groove. (Col. 4, ll. 15-20).

Thus, Applicants submit that all of the recited elements in independent claims 1 and 13 as amended herein are not found in Mercier, at least because Mercier fails to disclose a bag having “a first reinforced mating portion positioned adjacent to the central opening.” Applicants respectfully request withdrawal of the rejection of independent claims 1 and 13 in view of Mercier.

Dependent claims 2-12 depend directly or indirectly from independent claim 1. Dependent claims 14-23 depend directly or indirectly from independent claim 13. Accordingly, each of dependent claims 2-12 and 14-23 contain all the elements of their respective independent claims and are not anticipated by Mercier for at least the same reasons. Applicants respectfully request withdrawal of the rejection of claims 2-12 and 14-23.

**C. U.S. Patent Application Publication No. 2002/0107131 to Jorgensen *et al.***

Claims 1-29 and 34 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0107131 to Jorgensen *et al.* (hereinafter Jorgensen *et al.*). Applicants respectfully submit that claims 1-29 and 34 as amended herein are not anticipated by Jorgensen *et al.*

As an initial matter, at least one of the Applicants in the present case is also a joint inventor of the Jorgensen *et al.* application. Applicants note that the present invention represents an improvement over the disclosure of Jorgensen *et al.* at least in that Applicants’ present invention includes a first reinforced mating portion integrally formed for mating in a cooperative arrangement with a corresponding second mating portion of a hub and extending in a direction perpendicular to the interior surface. Contrary to Examiner’s assertion, Jorgensen *et al.* fails to disclose, teach or suggest that the bag includes either an integrally formed for mating in a

cooperative arrangement with a corresponding second mating portion of a hub or that the first mating portion extends in a direction perpendicular to the interior surface, as recited in Applicants' claims.

Prior art centrifuge processing bags, such as those described in U.S. Patent Application Publication No. 2002/0107131 to Jorgensen *et al.* do not include a first reinforced mating portion integrally formed for mating in a cooperative arrangement with a corresponding second mating portion of a hub, nor does the first mating portion extend in a direction perpendicular to the interior surface. As a result, the prior art bags are susceptible to slippage at the joint between the bag and the hub in the presence of centrifugal forces. The centrifugal forces experienced by the fluid-filled bag pull the prior art bags away from the hub. Without a first reinforced mating portion integrally formed for mating in a cooperative arrangement with a corresponding second mating portion of a hub and extending in a direction perpendicular to the interior surface, the prior art bags are prone to slippage at the joint to the hub. Beneficially, Applicants' first reinforced mating portion being reinforced for mating and extending in a direction perpendicular to the interior surface provides a more reliable technique for joining a centrifuge processing bag to a central hub. Centrifugal forces tend to pull a portion of the bag adjacent to the central opening radially outward. An interference fit obtained between the first reinforced mating portion when coupled to the second mating portion of the hub prevents movement of that portion of the bag adjacent to the central opening.

The Office Action at pg. 4, lines 14-17 mischaracterizes the Jorgensen *et al.* reference as including a first mating portion comprising one or more recesses formed adjacent to the opening, and again as including a first mating portion comprising one or more raised areas formed adjacent the openings. The Office Action relies especially on FIG. 1. The Office Action also relies on FIG. 1 for illustrating a gab comprising at least one weld ring.

To the contrary, Jorgensen *et al.* provides no such support for a bag having a first mating portion integrally formed for mating in a cooperative arrangement with a corresponding second mating portion of the hub and extending in a direction perpendicular to the interior surface of the bag. FIG. 1 does show a substantially circular enclosure including a first side and a second side radially

connected to the first side along an outer edge, the first and second sides defining an interior surface therebetween, at least one of the first and second sides having a central opening for housing a central hub.

Perhaps the Office Action misinterprets annular lines drawn about the central opening. There is no description of these lines as relating to any such first mating portion integrally formed for mating or extending in a direction perpendicular to the interior surface. Diagrams of the processor bag mounted on a hub are provided in FIG. 3 and FIG. 7 of Jorgensen *et al.*. Applicants note that these figures do not illustrate any first mating portion integrally formed for mating and extending in a direction perpendicular to the interior surface is observable. Rather, the portion of the bag adjacent to the axial opening and the hub appears to be positioned in a flat but joint against an adjacent surface of the hub.

In comparison, an exemplary embodiment of Applicants' invention illustrated in FIG. 2C plainly shows a first mating portion in the form of a half-round O-ring integrally formed to the bag extends in a direction perpendicular to the interior surface. The first mating portion of FIG. 2C is integrally formed for mating in a cooperative arrangement with a corresponding second mating portion of a hub shown in FIG. 3B. As further illustrated in Applicants' FIG. 6A and 6B, the first mating portion of the bag protrudes from the interior surface for extending into the recess of the adjoining hub when so joined (in the vicinity of reference 612a).

The Office Action at pg. 8, item 10 refers to the outer expressor bag 96 as being "integrally welded" to the outer weld ring 100, as shown in FIG. 11 of Jorgensen *et al.* The Office Action erroneously concludes that this arrangement anticipates Applicants' claims, which recite in pertinent part that a bag for use in centrifugal processing has:

a first reinforced mating portion positioned adjacent to the central opening, along the interior surface of at least one of the first and second sides, and extending in a direction perpendicular to the interior surface, the first reinforced mating portion integrally formed for mating in a cooperative arrangement with a corresponding second mating portion of a hub

The outer weld ring 100 described by Jorgensen *et al.* is not part of the bag. Rather, the outer weld ring 100 is part of a bag assembly that includes two bags: an outer expressor bag 96 and an inner processing bag 98. Neither of these prior art bags 96, 98 includes an first mating portion positioned

adjacent to the central opening, as recited in Applicants' claims. In order to secure the bags to the hub, Jorgensen *et al.* provides other separate components that are distinguishable from the bags. Namely, the outer weld rings 100 and the inner weld rings 102. It is these weld rings 100, 102 that secure the bags to the hub 104, and not any, so called, mating portion of the bag itself. (¶0050 at pg. 4) These weld rings 100, 102 would more appropriately be considered as part of the hub 104, since they are used to sandwich against the hub, a mating portion of the bag positioned adjacent to its central opening. Thus, by positioning the bag over the hub, and then applying the weld ring to the hub a portion of the bag is captured therebetween. There is nothing in Jorgensen *et al.* to suggest that the weld rings are in any way an integrally formed feature of the bag (i.e., they aren't shown or described as being attached to the bag alone.

Thus, Applicants submit that all of the recited elements in claims 1-29 and 34 as amended herein are not found in Jorgensen *et al.*, at least because Jorgensen *et al.* fails to disclose a bag that includes "a first reinforced mating portion integrally formed for mating in a cooperative arrangement with a corresponding second mating portion of a hub" and the first reinforced mating portion "extending in a direction perpendicular to the interior surface." Applicants respectfully request withdrawal of the rejection of claims 1-29 and 34.

### **Rejections Under 35 U.S.C. § 103**

#### **A. U.S. Patent Application Publication No. 2002/0107131 to Jorgensen *et al.***

U.S. Patent Application Publication No. 2002/0107131 to Jorgensen *et al.* claims 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen *et al.* The Examiner asserts that Jorgensen *et al.* teaches by implication, a process of welding a bag to a weld ring through solvents or heat. Assuming *agruendo* that it does, Jorgensen *et al.* still does not teach or suggest a bag having a first reinforced mating portion integrally formed for mating in a cooperative arrangement with a corresponding second mating portion of a hub as recited in amended claim 34 from which claims 35-38 depend directly or indirectly. Since the first reinforced mating portion integrally formed for mating in a cooperative arrangement with a corresponding second mating portion of a hub is part of the bag being welded to the second mating portion on the hub, Jorgensen *et al.* can't be read as

disclosing the claimed method of sealing a centrifuge bag to the hub. Accordingly, Jorgensen itself cannot be used to establish *prima facie* obviousness against the claimed invention. Applicants respectfully request withdrawal of the rejection of claims 35-38.

**B. Jorgensen *et al.* in view of U.S. Patent No. 3,982,691 to Schlutz**

Claims 30, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen *et al.* in view of U.S. Patent No. US 3,982,691 to Schlutz (hereinafter Schlutz). Applicants respectfully submit that claims 30, 32 and 33 as amended herein are not obvious over Jorgensen *et al.* in view of Schlutz at least because the references when combined fail to disclose, teach, or suggest all of the elements of the claims.

Independent claim 30 as amended herein recites “a first reinforced mating portion integrally formed for mating in a cooperative arrangement with a corresponding second mating portion of a hub.” As argued above, Jorgensen *et al.* fails to disclose, teach, or suggest at least this limitation. The Examiner characterizes Schlutz as teaching the use of adhesives to join the centrifuge bag components, but it does not offer Schlutz with respect to any particular distinctive elements of the centrifuge bag component itself. Thus, Schlutz does not cure the deficiencies of Jorgensen *et al.*, which does not itself disclose Applicants’ claimed centrifuge bag, *i.e.*, when taken in combination, the two references do not disclose, teach, or suggest Applicants’ claimed invention. Since Jorgensen *et al.* and Schlutz in combination do not disclose each and every element of the claimed invention, these two references, alone or in combination cannot be used to establish *prima facie* obviousness against Applicants’ claimed invention. Applicants respectfully request withdrawal of the rejection of claims 30, 32 and 33.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.



The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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